DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Stephanix Radiological Solutions
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

October 10, 2015

Re: K150306
Trade/Device Name: D^2RS_AT Digital Dynamic Remote System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: September 2, 2015
Received: September 9, 2015

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150306

Device Name
D^2RS_AT Digital Dynamic Remote System

Indications for Use *(Describe)*

The D^2RS_AT Digital Dynamic Remote System Is indicated for use in generating fluoroscopic images of human anatomy for diagnostic procedures. It Is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY K150306

Stephanix Radiological Systems
Rue Jean Moulin - ZI du Bayon
La Ricamarie - FRANCE
Tel : + 33 4 77 47 81 60, Fax : + 33 4 77 37 55 19

D²RS_AT Digital Dynamic Remote System

Date Prepared	August 6, 2015
Summary prepared by:	Sandie Perret, Quality Manager
Device Name/Trade Name	D²RS_AT Digital Dynamic Remote System
Common Name	Image-intensified fluoroscopic x-ray system
Classification	Class: II, Product Code: JAA Regulation: 21 CFR § 892.1650 Regulation name: Image-intensified fluoroscopic x-ray system
Identification of Predicate Device, Classification regulation, classification name and product code	Stephanix D²RF Digital Dynamic Remote System, K102529 21 CFR § 892.1650, System, x-ray, fluoroscopic, image-intensified and system, x-ray, angiographic, Product Code JAA

Device Description

The D2RS_AT Digital Dynamic Remote System is a direct digital dynamic remote-controlled fluoroscopy and radiography system equipped with the latest generation of Trixell Flat Panel Detector (FPD). The single FPD can perform both fluoroscopy and radiography and is detachable and portable for direct projections to create a unique and highly versatile 3-in-1 imaging solution. The receptor panel directly converts the X-ray images captured by the sensor into a high-resolution digital images. The instrument is suited for use inside a patient environment. This unit converts the X-rays into digital signals. The unit can acquire still and moving images. The system includes a remotely controlled tilting/elevating table. Panel information: Based on a flat-panel digital detector with the largest field-of-view in the market, the Pixium RF 4343 FL is designed for easy integration in classical R&F tables. It allows manufacturers to offer radiologists an all-digital real-time system, generating high-quality images for both routine dynamic applications and high-end static ones. Digital technology facilitates the work of X-ray technicians and speeds up the process, allowing medical centers to optimize patient throughput. Universal: a single detector for both Radiography and Fluoroscopy. An optional static panel may be added to the system: Trixell Pixium 3543EZ. The 3543EZ panel has already been cleared in various 510(k)s including K131314 and K141440. That panel is not mounted and can be moved around by the technician. The system must always have either the Pixium RF 4343, Pixium RF 4343FL for the system to be able to perform fluoroscopy. These fluoroscopic panels were not to our knowledge previously cleared by FDA, so complete performance information as requested by the FDA guidance document on solid state x-ray panels has been provided.

Indications for Use	The D²RS_AT Digital Dynamic Remote System Is indicated for use in generating fluoroscopic images of human anatomy for diagnostic procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

Technological Characteristics and Substantial Equivalence	Comparison with the predicate shows the technological characteristics of theD^{2}RS_AT Digital Dynamic Remote System are equivalent to the predicate device because the images produced by the new panels have equivalent image quality, MTF, DQE, and safety test results. The units are functionally identical. Only the digital panel and the connected computer have changed.

Comparison Table

	D^{2}RF K102529	D^{2}RS_AT Digital Dynamic Remote System
Indications Statement	The D^{2}RF Digital Dynamic Remote System is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.	The D^{2}RS_AT Digital Dynamic Remote System Is indicated for use in generating fluoroscopic images of human anatomy for diagnostic procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.
Photo of Digital Panel		
DICOM 3	YES	YES
Workstation Photo(s)		

Digital Panel Comparison Table

Name	CXDI-50RF (Predicate K102529)	Pixium RF 4343 (NEW)	Pixium RF 4343 FL (NEW)
Dimension	493 x 503 mm	508 x 518 mm	500 x 490 mm
Useful Area	360 x 430 mm	426 x 420 mm	426 x 420 mm
Type of conversion	Indirect	Indirect	Indirect

Name	CXDI-50RF (Predicate K102529)	Pixium RF 4343 (NEW)	Pixium RF 4343 FL (NEW)
Scintillator	CsI	CsI	CsI
Pixel pitch	160 µm	148 µm	148 µm
Spatial resolution	3,2 lp/mm	3,4 lp/mm	3,4 lp/mm
Matrix	2208 x 2688	2874 x 2840	2874 x 2840
AD conversion	14 bits	16 bits	16 bits
DQE	72% (0 cy/mm) 60% (1 cy/mm) 42% (2cy/mm) 24% (3cy/mm)	65% (0 cy/mm) 52% (1 cy/mm) 42% (2cy/mm) 28% (3cy/mm)	65% (0 cy/mm) 52% (1 cy/mm) 42% (2cy/mm) 28% (3cy/mm)
MTF	57% (1 cy/mm) 32% (2cy/mm) 18% (3cy/mm)	62% (1 cy/mm) 25% (2cy/mm) 18% (3cy/mm)	62% (1 cy/mm) 25% (2cy/mm) 18% (3cy/mm)
Fps Max	30 fps	30 fps	30 fps
Binning max	2 x 2	3 x 3	3 x 3
Operating temperature	5- 35°C	15-40°C	15-40°C
Optional Panel	Not Applicable	Pixium 3543 EZ, Static Panel cleared in K142718	

Bench/Performance Testing/Data	Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device. Tests included: Performance testing and Software Validation. Electrical safety and Electromagnetic Compatibility testing has been performed. The unit complies with the US Performance Standard for radiographic equipment. We assessed and showed conformity to IEC 60601-1, IEC 60601-1-3, IEC 60601-2-54, IEC 60601-1- 2, 21CFR Subchapter J as well as the DICOM 3 Standard. We also assessed compliance with the guidance document, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices." The MTF and DQE comparisons in the table above show the new digital panels perform better in some measurements and slightly worse in other measurements, but such numbers should be compared with caution because of measurement uncertainty error. Spatial resolution and pixel pitch are superior for the new panels. The device conforms to the requirements of the DHHS performance standard pursuant to 1020.30, 1020.31 and 1020.32.
Clinical Evaluation	In accordance with the guidance document, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices," a board certified radiologist reviewed both static and moving images and found them to be of good diagnostic quality.
Conclusion	Based on our comparison of technological characteristics and our bench and clinical results, our conclusion is that the modified system is as safe and effective as our predicate device and is therefore substantially equivalent.